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INTRODUCTION

Welcome to purchase and use our Patient Warmer System. The device was developed according to clinical needs and meets the requirements of the latest safety regulations. This manual includes the operation and use instructions of Patient Warmer System (PWS-02) and the technical specifications of the product. Before using this device, please be sure to read all the instructions carefully and fully understand the precautions for the use of forced air warming device. Keep this manual safe so that all users can refer to it at any time. The equipment shall be used under the intended conditions and purposes specified in this instruction manual and in the manner intended for use under the operation or guidance of a professional. If you have any questions, comments or suggestions during use, please feel free to feedback to us.

I. Scope of application

In the clinical use environment of medical institutions, by controlling the temperature of the warming blanket, it has the function of physically warming the human body in vitro, and achieves the purpose of assisting the adjustment of human body temperature. The Patient Warmer System is suitable for adults, children, babies and animals.

II. Contraindications

a. Do not use on open wounds. Wrap the wound well when heating.
b. Not applicable to ischemic limbs. Heating up an ischemic limb maybe cause burns.
c. Patients with vascular surgery should be cautious or stop using when the artery is blocked (such as the aorta is blocked). The patient's lower extremities should not be heated during arterial cross-clamp.
d. For use with severe peripheral vascular disease, caution and close monitoring should be exercised.

III. Notice before use

The devices can be used safely and with confidence, providing reliable service and high-quality patient care. When setting and adjusting the temperature of the machine according to the patient's physical signs and specific conditions, it must be operated by professional medical personnel. Please read and understand the following instructions carefully before using the device.

WARNING

NO	In the following dangerous situations, if not avoided, could result in death or serious injury.
1	The device can only be safely operated with the matching surface warming blanket. Using it with other brands' products may cause burns. (To the fullest extent permitted by law, we are not responsible for burns caused by the use of accessories not provided by our company, including blankets, mat blankets, power cords, and air ducts).
2	When warming a patient, do not let them lie on the air duct or allow the air duct to directly contact their skin, as it may result in heat injury.
3	Using the air duct alone to warm a patient may cause heat injury; always ensure the air duct is connected to the warming blanket before use.
4	Babies, toddlers, children, and other vulnerable patients must be supervised during warming therapy.
5	When in use, ensure that the warming blanket is not reversed; the light-colored layer should face the patient for proper ventilation, as reversing it may cause burns or inadequate warming.
6	Do not connect torn or damaged warming blankets to the devices.
7	If a high or low temperature warning appears on the display screen and an audible alert is heard, the surface warming therapy must not be continued. Continuing the treatment could cause harm. If the alert sound persists, unplug the power cord of the warming device and contact a qualified service technician.
8	Do not use warming blankets above skin-penetrating patches as it may lead to increased drug dosage, patient injury, or death.
9	Do not cover the patient's head or airway with a warming blanket if mechanical ventilation cannot be achieved.

10	Do not use a warming blanket to transfer or move patients, as it may result in patient falls and injuries.
11	To reduce the risks associated with dangerous voltage and fire hazards, please pay attention to the following: a. Always keep the wires visible and easily accessible. Plugs on the wires are used to disconnect power to the device. b.Only connect to receptacles marked "for medical use only" or "medical grade" or reliable grounding receptacles. c. Use only the power cord specified for this product and certified by the country/region of use. d.Do not let the power cord get wet. e. Except for qualified service personnel, no one else should dismantle the device. Even when the device is connected to power in standby mode, there are live components inside the device, posing a risk of electric shock. f. Do not use this device when the main unit or any component is damaged. Please contact the after-sales or technical service for replacement or repair.
12	During prolonged warming therapy, patients must not be left unmonitored as it may lead to heat injury.
13	The use of non-inflatable warming device power cords and replacement parts can result in increased radiation or reduced interference resistance.
14	While the device is in use, there is a risk of electrical shock, burns, or electromagnetic interference when using high-frequency devices for surgery or intracardiac catheter procedures.
15	it is not suitable for use during magnetic resonance imaging observation, as it may affect the MRI images.
16	Do not cover the skin surface with dermal material during ventilation heating.
17	Do not use consumables other than warming blankets during ventilation heating to avoid causing heat injury.
18	The blankets should not be used with devices other than inflatable warming machines to prevent heat injury.
19	Covering parts or all of the device with pillows, blankets, etc., may cause the safety system to fail, resulting in heat injury.

CAUTION

NO	If the following dangerous situations are not avoided, they may result in minor or moderate injuries.
1	The surface warming blanket component of the device is non-sterile. Each warming blanket is for single patient use only; otherwise, there is a risk of cross-contamination, and it can be reused for the same patient throughout the entire perioperative period if necessary. Placing a bed sheet between the warming blanket and the patient does not prevent contamination of the product.
2	To reduce the risk of cross-contamination, the exterior of the device and air ducts should be cleaned after each patient use.
3	It is recommended to continuously monitor the patient's body temperature. If continuous monitoring is not possible, monitor the temperature and skin reactions of patients who cannot respond independently, communicate, or have no sense of temperature every 10-20 minutes or according to hospital protocol, and regularly monitor the patient's vital signs. Adjust the temperature of the warming device or discontinue treatment when the treatment goal is reached, adverse skin reactions occur in the warming area, or if there are unstable vital signs. Notify a doctor immediately if unstable vital signs are detected.
4	Do not place the host on a soft, uneven surface like a bed, or on a damp surface, as it may obstruct air intake and affect performance. Only when the warming device is securely placed on a hard surface, or securely fastened to an IV stand, bed rail, cart, or mobile stand, can the warming therapy be initiated to prevent injury.
5	When clamping host in the IV stand, ensure the height allows for stability. It is recommended that the base diameter of the IV stand is not less than 71cm, with a fixed height (top of host to ground) not exceeding 112cm. Failure to comply with these requirements may result in IV stand tipping over, damage to the air duct insertion, and patient injury.
6	The device should not be used or stored together with other equipment. Portable and mobile RF (Radio Frequency) communication devices will affect normal functionality.
7	The electromagnetic interference of the device complies with IEC 60601-1-2 (YY 0505). However, if interference from other devices occurs, users should refer to the following methods to eliminate the interference. a. Turn off nearby devices and isolate the interfering device. b. Adjust or relocate other receiving devices.

	c. Increase the distance between the device and the interfering device, and use a different power outlet. d. For assistance, please contact your local distributor or after-sales service unit.

ATTENTION

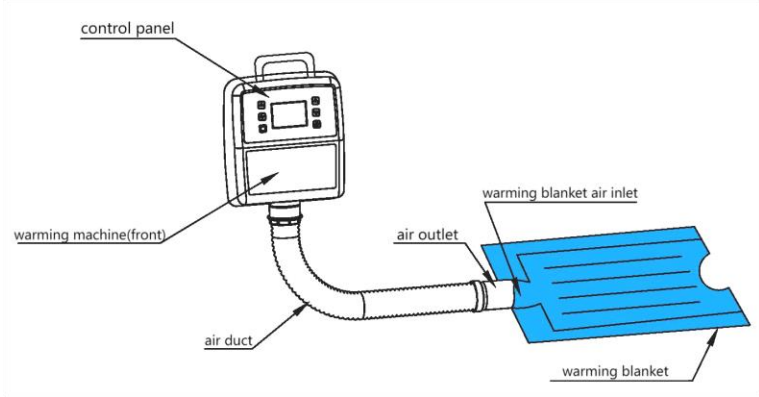
NO	If the following situations are not avoided, they may only result in financial loss or affect usability.
1	The device meets the requirements of medical electrical interference. In case other devices experience radio frequency interference, please connect this device to a different power source.
2	The device is equipped with an air filter, and air pollution should be considered during use.
3	To prevent damage to the inflatable warming device, the following precautions should be noted: a. Use the correct electrostatic discharge procedure during maintenance. b. Do not modify this equipment without authorization from the manufacturer. c. Do not immerse the host, parts, or accessories in any liquid or subject them to any sterilization treatment. d. Do not use cleaning solutions containing alcohol, acid-base cleaners, or solvents (including acetone or diluents) with concentrations higher than 80% to clean the host and air ducts, as solvents may damage labels and other plastic parts.
4	Before using the device, please check the surface of the equipment for any mechanical damage.
5	When replacing the connecting air duct, be careful not to damage the temperature sensor of the air duct.
6	To minimize environmental pollution risks, please follow applicable regulations for disposing of this equipment or any electronic components.
7	Do not attempt to clean the air filter as it may become contaminated during use and should be handled according to hospital regulations.
8	The back of the device is the air inlet. Please do not allow objects such as paper, film, powder, etc., near the bottom of the main unit, as this may affect the normal operation of the main unit.
9	After starting the air device, please ensure not to block the air outlet of the air duct, as this may affect the normal operation of the main unit.
10	The temperature probe must use products provided by this company, as using others may affect the temperature monitoring function.

	Operate and use the temperature probe strictly according to the operation method, precautions, and other requirements in the temperature probe manual.
11	When monitoring temperature, choose the probe type correctly. There are two types of probes: surface and cavity. The surface temperature probe is commonly used for measuring temperature under the armpit, while the cavity temperature probe is commonly used for measuring temperature in the mouth or rectum.
12	Do not secure the temperature probe in areas where the patient has tissue damage.
13	The temperature probe is only used for temperature indication, not for controlling the heater's power, setting the patient's target temperature, or for diagnostic and monitoring purposes.

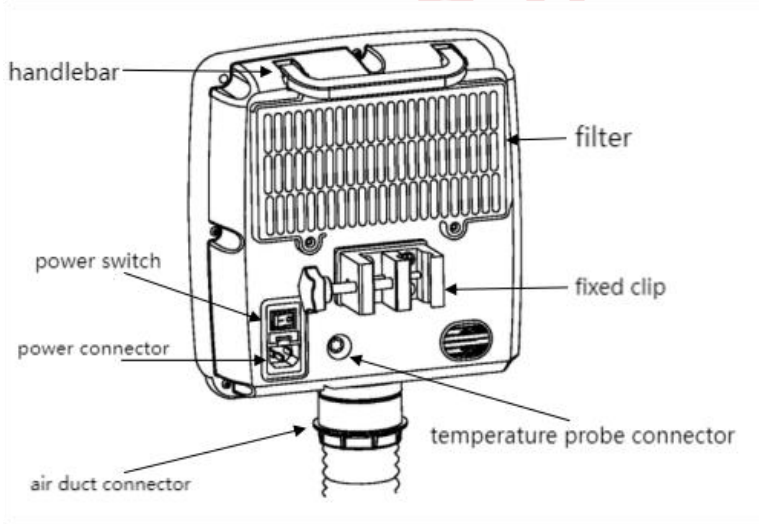
IV. Main structural composition

1. Patient Warmer System composition

The Patient Warmer System mainly consists of an inflatable warming machine and a surface warming blanket. The inflatable warming machine is mainly composed of a heating device, a temperature sensor, a power circuit board, a control circuit board, a blower and a body temperature probe (optional). The inflatable warming machine can only be used with a series of single-person single-use warming blankets. (Refer to Figures 1 and 2 for the main structural composition of the inflatable warming machine.)



Figures 1 Frontal Schematic



Figures 2 Back Schematic

2. Description of control panel of inflatable warming machine

2.1 Control panel of the inflatable warming machine is located on the front of the main unit and can be operated by pressing the buttons.

2.2 The operation of the inflatable warming machine is very simple. All settings can be seen on the panel of control buttons, and the desired temperature, air speed can be selected by touching each button.

Figures 3 A Control Panel

3. Description of the display screen

a. "Set Temp" window: Shows the current temperature setting level.
b. "Set wind speed" window: Shows the current wind speed setting level.
c. "Set Body Temp" window: Shows the current upper and lower limits of the set body temp.
d. "Current Temp" window: Shows the real-time temperature at the device's air duct outlet, with a temperature display accuracy of 0.1°C. In case of a malfunction alarm, the "Current Temp" window changes to "Malfunction Alarm".
e. "Current Body Temp" window: Shows the real-time temperature of the current body temperature probe, with a temperature display accuracy of 0.1°C. When the probe measurement range is exceeded, it displays 00.0°C.
f. "Room Temp" window: Shows the current temperature inside the equipment compartment.

g. "Operation Time/Working time" window: Shows "Operation Time" every time the device is turned on, which is the cumulative running time since the device left the factory, in hours. After 5 minutes of operation, it changes to "Working time," which is the timing of the working time after the device is turned on this time, in units of 000-00.

h. Working Status" window: Shows various minor malfunction or maintenance prompts.

V. User Instruction

1. Prepare to use

1.1 ⚠ **WARNING** , Before using the device,the following preparations should be made:

a. Inspect the main unit,power cord,and air duct of the inflatable warming machine for any damage,and do not use it if any damage is found.

b. The main unit should be securely fastened to the infusion stand,hospital bed rail,cart, dedicated caster stand,or placed on a hard surface. Avoid placing it on a soft or uneven surface,such as a bed,to prevent blockage of the air inlet leading to device overheating.

c. Do not obstruct the air inlet (the air inlet and filter are located at the back of the warming machine).

1.2 The main unit and air ducts are already assembled at the factory and are ready to work as soon as they are powered on. In case the air ducts are damaged, they can be replaced under the guidance of a technician.

1.3 The warming blanket is a vulnerable accessory used in conjunction with the device, connected to the air outlet of the main unit's air duct to provide the user with a heated airflow after warming up. Choose the appropriate model and specification of blanket based on the type of patient and surgical needs. The warming blanket is divided into two types, with the cover blanket represented by "M," covering the patient, and the under blanket represented by "W," placed under the patient.

2. Connect the warming blanket

2.1.1 Open the packaging and lay out the warming blanket according to the directions, ensuring that the light-colored non-woven fabric faces the patient.

2.1.2 Insert the machine's air outlet duct into the warming blanket's air inlet, securely fasten it, and secure the duct joint at the rear with Velcro or straps to prevent it from detaching.

2.1.3 Ensure the air duct of the device is laid out flat and tidy.

3. Connect the power supply
   a. Insert the power cord plug end into the main unit power connector, ensuring a secure firmly.
   b. Connect the device power cord plug end to a power outlet with good grounding.
   c. Connect the temperature probe interface end to the device's temperature probe interface (refer to Figure 2), ensuring a secure connection.
   d. Securely position the temperature probe measuring end at the patient's temperature monitoring location and place the cable in a position that does not interfere with the measurement and ensures patient safety. The temperature probe should not be secured to areas of organized injury on the patient.
   e. If the temperature probe is unable to accurately monitor temperature, it indicates an improper position or insecure placement. In such cases, reposition the probe or select a different model.
   f. Power on the device, turn on the power master switch (refer to Figure 5), initiating the device's self-check (After the display screen and indicator lights are all on, the self-test for high and low-temperature alarm functions at the air outlet will begin.). Once the self-check is complete, the device enters standby mode, with the operation indicator light blinking and the display turned off.

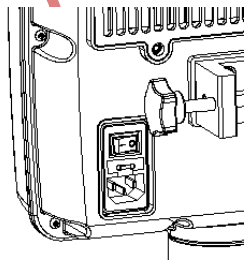


Figure 5 Bottom power supply main switch position indication diagram

4. Start the device and heat the body surface
   1)Temperature setting method: When turned on, it defaults to the temperature setting function. Press the "▲" or "▼" buttons on the adjusting side, the display screen will show "Set Temperature" blinking. For model B, temperature can be set from 32℃ to 43℃, with a 0.5℃ step adjustment. When the lowest temperature is reached and further adjusted, it will display

as "Room Temperature". After adjusting, if no buttons are pressed, the settings will be automatically saved after 2 seconds.

2)Wind speed setting method: Press the "settings" button, the display screen will show the blinking words "set wind speed", press the "▲" or "▼" buttons on other side to switch between low, medium, and high speeds, the settings will be automatically saved after 2 seconds.

3)Method for setting upper and lower limits of body temperature: Press the "Set" button again, the display will show "Set upper temperature limit" or "Set lower temperature limit" flashing, press the"▲"or"▼"button on other side to set the desired upper limit or lower limit. Adjust the step size to 0.1°C, press and hold for quick increase or decrease. Settings will be saved automatically after 2 seconds.

Note: The upper and lower temperature limit alert function will only be activated when the "current temperature" exceeds 28°C and is maintained for 3 minutes.

4)If the operating process needs to be adjusted again, repeat the above steps in order to set the temperature, wind speed, upper body temperature limit, and lower body temperature limit again. Switching while saving the previous setting data.

5)Method of setting the timed shutdown:

① Press the "Timing" button, the display will change from "Room temp" to "Timed shutdown". The time display unit is 000-00 (hours-minutes), and the default timed shutdown time is 2 hours. If there is no adjustment within 4 seconds, the default time shutdown will be executed automatically.

② If you need to adjust the timed time, you should, within 4 seconds, press the "▲"or"▼"to adjust the time. The display "Timed shutdown" flashes, and the adjustment step is 10 minutes. Long press"▲"or"▼"for quick increase or decrease. The time is displayed in countdown manner. After adjusting, if no button is pressed, the settings will be automatically saved after 4 seconds, and the "Timed shutdown" text stops flashing.

③ During the timed shutdown process, pressing the "Timing" button can adjust the timed shutdown time again. Long press the "Timing" button for 2 seconds to disable the timing function.

d. The gear cannot be circulated, and can only be selected by pressing"▲"or"▼".

e. When selecting the "room temp" setting, the internal heater of the device does not work, and directly outputs indoor temperature air.

f. When the temperature setting decreases from high to low, due to the heat storage inside the main unit, there may be a cooling process. The duration of this process varies depending on the temperature difference, and is considered a normal phenomenon.

g. Warning: Do not use the device when the duct is not connected to the warming blanket to avoid heat damage.

5. Heating process monitoring

As per protocol, monitor the temperature and skin response of the patient who is unresponsive, non-communicative, and/or insensate every 10 to 20 minutes. Regularly check the vital signs of the patient. Ensure the patient does not experience skin warmth or redness. Adjust the warming temperature or discontinue the treatment when the therapeutic goal is reached or if vital signs become unstable. Notify the physician immediately in case of unstable vital signs.

6. Stop heating treatment after running

a. Press the "On/Off"button to turn off the device, and it will be in standby mode.

b. Remove the temperature probe, if it is for one-time use, it should be disposed of as medical waste.

c. Disconnect the air duct from the warming blanket, remove the warming blanket from the patient, dispose of it as medical waste, and discard the disposable parts.

d. Turn off the power switch of the device, then unplug the power cord from the power outlet.

e. It is recommended to cut off the power when not using this device for a long time.

VI. Security system and alarm

1. The device is equipped with a visual and auditory fault alert system, providing better indication of system malfunctions. Operators can identify fault alarms and prompts appearing directly in front of the device.

2. In case of the following two fault scenarios during operation, the system will display the corresponding fault codes and alarm information in red flashing in the "Current Temp" window. The alarm sound pressure can reach ≥65dB(A) at a distance of 3 meters, and users should promptly address the issue according to the troubleshooting methods.

Table 1 Explanation of Fault Alarms

Fault Code	Alarm Information	Alarm Level	Fault Alarm Content	Device Status	Resolution Method
E11	Air Outlet Low Temperature	High priority	start heater C after the failure of heater AB, and the outlet temperature can not reach the set temperature for 3 minutes, or the outlet temperature of heater C is lower than the set value minus 2.0°C during the normal operation. Any of the above two conditions will be fault alarm.	All internal heaters and blower of the device will immediately cease operation.	Switch off the power, wait for 5 minutes before restarting the warming device. If the fault persists, please stop using the device for further use, terminate all surface heating treatments, disconnect from the warming blanket, and promptly contact the after-sales or technical service personnel.
E21	Air Outlet High Temperature		1. High temperature over temperature alarm: Outlet temperature exceeding 42°C under any circumstance. 2. High-temperature alarm: Outlet temperature exceeds the set value by 2.0°C after 3 minutes of device startup or temperature adjustment.		

3. When the following fault conditions occur during operation, the system will display the corresponding fault codes and prompt information in yellow in the "Working Status" window.

Table 2 Fault Prompt Explanation

Fault code	Alarm Information	Fault Alarm Content	Device Status	Resolution Method
E41	Sensor A Malfunction	After power on, sensor A or sensor B output signal can't be detected.	Switch automatically to another sensor; if the other sensor is functioning properly, the device will continue operating.	The other sensor is only for emergency use; please contact after-sales or technical service personnel promptly to replace the faulty sensor at the earliest opportunity.
E42	Sensor B Malfunction			
E43	Sensor AB Malfunction	Temperature sensors A and B fail to work properly at the same time.	All internal components of the device stop working immediately.	Switch off the power, wait for 5 minutes before restarting the warming device. If the

E33	Heater Malfunction	If the device is just started or the temperature level is adjusted, and the outlet temperature does not reach the set temperature within 3 minutes, or if the heater's outlet temperature falls 2.0℃ below the set value during normal operation, a prompt will be given for any of the above situations.	All internal heaters and blower of the device stop working instantly.	fault persists, please refrain from further use, terminate all surface heating treatments, disconnect from the warming blanket, and promptly contact the after-sales or technical service personnel.
E51	Blower Malfunction	After turning on, no blower output signal detected.	All internal heaters of the device cannot start.	

4. When other situations occur during operation, the system will display the corresponding prompt message in yellow in the "Working Status" window.

Table 4 Other Prompt Explanation

Alarm Information	Fault Alarm Content	Device Status	Resolution Method
Recommended to change the filter.	The heater has been running for a total of 1000 hours.	The machine can be used normally, restart, if the issue persists, continue with maintenance instructions.	Timely replacement of efficient filters is essential to ensure the performance of the equipment.

Temperature above the set upper limit.	The temperature sensor detected that the patient's current temperature is higher than the set upper limit and remained so for 3 minutes.	The machine can be used normally, and the display screen currently changes to yellow indicating temperature.	Adjust the temperature setting based on the patient's current body temperature and condition. If the body temperature remains above or below the set limits after adjustment, other clinical intervention measures should be taken promptly.
Temperature below the set lower limit.	The temperature sensor detected that the patient's current temperature is lower than the set lower limit and remained so for 3 minutes.		

Note: The normal working process refers to starting the equipment or after adjusting the temperature for 3 minutes.

VII. Storage cleaning and maintenance

1. Store
   The inflatable heating device and its accessories are stored in an environment with a relative humidity not exceeding 80%, free from corrosive gases, cool, dry, well-ventilated, and clean.
2. Proper use and maintenance
   2.1 ⚠ Warning, our company shall not bear any responsibility for the reliability, performance, and safety of the device under the following circumstances:
   a. Modifications or repairs are carried out by unqualified personnel.
   b. Use this device in ways other than those described in this manual.
   c. The environment in which the device is installed does not comply with the relevant electrical and grounding requirements.

d. Failure to operate and maintain the device as described in this user manual.

2.2 ⚠ Warning, users are not allowed to repair any components of the device. When thedevice malfunctions, users should not attempt to repair or open it, as this may result in damage to the device and render the warranty invalid. Repair and maintenance of this device must be carried out by personnel familiar with medical device repair, experienced, and possessing thenecessary skills.

3. Clean

3.1 Cleaning Steps

a. Before cleaning, it is essential to disconnect the power supply of the device.

b. Clean according to hospital cleaning standards. After each use, wipe the main unit, duct exterior, and any other surfaces that may be touched with a soft damp cloth and approved neutral cleaner.

c. Air dry or use a separate clean soft cloth to dry after cleaning.

3.2 ⚠ Warning, his device's cleaning and maintenance should pay attention to the following points:

When cleaning, do not immerse the host, components, or accessories in any liquid or subject them to any sterilization treatment. Moisture can damage components, leading to patient thermal injury.

Do not use a damp cloth to clean the chassis. Moisture may seep into electrical contacts and damage components.

Do not use alcohol, acidic or alkaline cleaning agents, or solvents (including acetone or diluents) with a concentration higher than 80% to clean the host and ducts, as solvents may damage labels and other plastic parts.

4. Replace the filter

a. The device has primary filter and high-efficiency filter. Under normal operating conditions, it is recommended to replace the primary filter every 1–2 months.

b. When the cumulative operating time of the heating device reaches 1000 hours, if the "Operating Status" window turns yellow and shows "Filter replacement recommended", restart the device. If

the situation persists, continue with maintenance prompts. At this point, the high-efficiency filter should be replaced promptly to ensure the equipment's performance.

c. To replace the filter, follow these steps:

1) Before replacing the filter, disconnect the power supply of the heating device.
2) Following the disassembly arrows shown in Figure 6, loosen the two screws to replace. Pay attention to the positive and negative sides of the high-efficiency filter.
3) After installing the new high-efficiency filter, reconnect the heating device to the grounding power supply and restart the equipment in the correct sequence.
4) Reset the "Operating Time", the display of "Filter replacement recommended" will disappear and return to normal.
5) If the device does not return to normal operation, please contact qualified after-sales or technical service personnel.

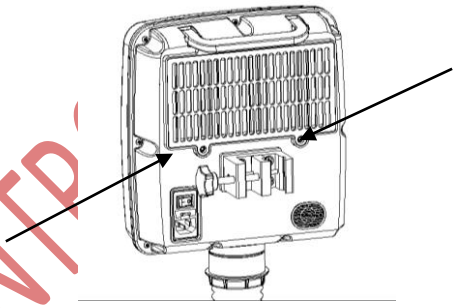


Figure 6 Disassembly and Assembly Air Filter Instructional diagram

VIII. Product life and warranty technical services

1. Production date.
   The production date of the Patient Warmer Systemcan be found on the product label.
2. Service life
   Under normal use and maintenance conditions, the minimum service life of the device is 10 years.
3. Accessories List

One air duct, one power cord, one blower, one set of heaters, one set of temperature sensors, one set of air filters, and one blankets are included.

4. Recommended Replacement Period for Accessories

4.1 If sensors A and their lines are damaged within three years of using the warming device due to non-human factors, they can be replaced for free.

4.2 The performance of sensors A may decrease after more than three years of use, it is recommended to replace them after three years to avoid affecting temperature accuracy.

4.3 If the air ducts are damaged or broken within three years of using the device due to non-human factors, they can be replaced for free.

4.4 If the device has been used for more than 1000 hours, it is necessary to replace the high-efficiency filter promptly to ensure the performance. Even if the operating time has not reached 1000 hours, the high-efficiency filter should be replaced annually as part of routine maintenance.

4.5 Under normal use, it is recommended to replace the primary filter every 1–2 months to ensure the device's performance.

5. Warranty Period

Under normal use and maintenance, free repair service is provided within one year from the date of shipment. However, device malfunctions or damage caused by improper use or self-disassembly are not covered by the warranty.

6. Repairs During the Warranty Period

If your heater requires factory repairs, please contact our company. During the repair of your device by us, you can contact your local supplier or sales representative to inquire if a heater can be borrowed. For more detailed information on returning device for repairs, please contact your local distributor

7. Technical Support and Service.

When you need to seek technical support from the after-sales technical service department or local supplier, please provide the product number, which is located on the label on the back of the heater.

8. Waste Disposal

Some materials contained in the device, such as electronic components, heating modules, connecting wires, motherboards, blowers, etc., comply with the provisions of the Electronic Information Product Pollution Control Standard SJ/T 11363-2006 "Limit Requirements for Harmful

Substances in Electronic Information Products." They do not contain lead, mercury, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers, cadmium, and other chemical components, and can be recycled and should not be discarded randomly.

IX. Product parameters

1. Physical characteristics
   - Dimensions: Height × Depth × Width: 28 cm × 12 cm × 25 cm
   - Weight: Approximately 3 kg
   - Relative Noise Level: Less than 55dB(A)
   - Double filtration system: Primary filter, 0.2 micron high-efficiency filter
   - **Recommended Replacement Cycle for High-Efficiency Filter**: Every 12 months or 1000 hours of use
   - **Installation Fixation**: Placed on a hard surface or securely secured to the holder of the device
2. Temperature characteristics
   - **Recommended operating environment**: Temperature (5–30)°C, relative humidity (30–75)%RH, atmospheric pressure (700–1060) hPa
   - **Temperature control**: Electronic control
   - **Operating modes**: Natural air mode and warming mode
   - **Operating temperature**: Average temperature at the end of the air duct:

     PWS-02 : (32–43) °C ±0.9 °C
   - **Time to reach the set temperature range**: Not exceeding 3 minutes
   - **Storage/transport temperature**: Store all components in a cool and dry place when not in use
3. Safety System
   - **High-temperature protection for air outlet**: When the temperature at the air outlet exceeds 45°C under any circumstances; or if the air outlet temperature exceeds the set value by 2.0°C after starting the device or adjusting the temperature level for 3 minutes, all internal heaters and blowers will stop working immediately.

- **Low-temperature protection for air outlet**: If the air outlet temperature cannot reach the set temperature within 6 minutes, or if the air outlet temperature is 2.0°C below the set value during normal operation of the heater C, all internal heaters and blowers will stop working immediately.
- **Overcurrent protection**: Double-input fuse circuit (fuse: F10AL 250V 5×20mm).
- **Fault indication**:
  - The display screen will show "fault code and fault alarm information" in the current temperature window.
  - The display screen's operating status window will show "fault code and fault indication information".

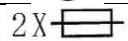
4. Electrical characteristics
   - **Heating Element**: Heating wire (mica support electric heating alloy wire heating module), 800W.
   - **Power Connection Requirements**: 220V~, 50Hz, 10A
   - **Power Consumption**: Peak: 900VA, Average: 400VA
   - **Leakage Current**: Complies with the requirements of IEC 60601-1
   - **Electromagnetic Compatibility**: Complies with the requirements of IEC 60601-1-2
   - **Blower Motor**: Operating speed: 3800 rpm, Airflow: 72 CFM
   - **Classification**: Classified according to GB 9706.1, this device is Class I, BF type ordinary ordinary equipment, continuous operation equipment, waterproof level IPX2, managed as Class II medical devices.
   - **Diagnosis**: Qualified maintenance technicians can perform overtemperature detection system tests, temperature output tests, operate temperature calibration, and fault information troubleshooting for the device.
5. Cable Information
   - **Power Cord**: 5.0 m 250VAC 10A or 5.0 m 250VAC 10A
   - **Temperature Probe Line**: 3 m
6. Software

   Software Name: Inflation heating machine control software

   Software Release Versions:

   ZB01B

X. Interpretation of symbol identification

	AC power
	Protective grounding
	Mark the fuse box and its location (2 fuses: F10AL, 250V, 5×20mm)
	BF type equipment
	Secure all ducts, do not warm the patient if there are no warming blankets
	Dispose of special waste separately, following European Directive 2002/96/EC (WEEE) or local regulations
	Free from or contains natural rubber latex
	Refer to user manual
	Warning
	Dangerous voltage Do not dismantle unless you are a professional. Internal components will be live when connected to power.
IPX3	When all vertical surfaces of the casing are inclined at 60°, vertical dripping water has no harmful effect.
	Sunscreen
	Fear moisture

	Handle with care
	Upwards
	Non-ionizing radiation

XI. Appendix A Instruction manual for body surface heating blanket

- Product name : Surface Temperature Heating Blanket
- Scope of applicatio : In the clinical setting of medical institutions, by controlling the temperature of the warming blanket, it has the function of physiologically warming the body temperature externally, achieving the purpose of assisting in regulating the body temperature.
- Product performance and structural composition
  a. The product is composed of polypropylene non-woven fabric and polyethylene film.
  b. A plastic film can be optionally selected and placed over the patient's head and legs according to surgical needs to further reduce the patient's heat loss.
  c. The product has uniform color, without obvious color difference, defects, stains, or damage, with an inlet width not less than 10cm.
  d. The temperature deviation between the inlet of the blanket and the outlet of the air duct: low temperature mode≤2.0°C,medium temperature mode≤3.0°C,high temperature mode≤3.5°C.
  e. The temperature deviation of the core area of the application site of the blanket and the outlet temperature of the air duct:the deviation of the three temperature modes of each model specification warming blanket is≤the corresponding temperature deviation value in the table below.

Usage type		Model specifications	Recommended operating wind speed	temp deviation		
				Low temp	Med temp	High temp
U	Torso blanket	U10080/100cm×80cm	Low speed	4.0	5.5	6.0

	Small lower body blanket	U11080/110cm×80cm	Low speed	3.0	4.5	4.5
	Lower body blanket	U13080/130cm×80cm	Low speed	3.0	4.5	4.5
	Upper body blanket	U19560/195cm×60cm	Low speed	3.0	4.0	4.5
	Paediatric blanket	U15080/150cm×80cm	Medium speed	3.0	4.5	4.5
	Shoulder blanket	U18080/180cm×80cm	Medium speed	3.0	4.5	4.5
	Outpatient blanket	U18580/185cm×80cm	Medium speed	4.0	5.5	6.0
	Full-body blanket	U19080/190cm×80cm	Medium speed	3.0	4.5	4.5
	Sleeveless belly blanket	U20080/200cm×80cm	Medium speed	3.0	4.0	4.5
	Larger sleeveless belly blanket	U20090/200cm×90cm	Medium speed	3.0	4.0	4.5
	Larger upper body blanket	U20580/205cm×80cm	Medium speed	3.0	5.0	6.0
	Multifunctional blanket	U19090/190cm×90cm	High speed	5.0	6.0	6.5
	Larger full-body blanket	U200100/200cm×100cm	High speed	5.0	6.0	6.5
	Belly blanket with sleeves	U200195/200cm×195cm	High speed	3.0	4.5	4.5
D	Neonatal full-underbody blanket	D9080/90cm×80cm	Low speed	3.0	5.0	6.0
	Neonatal underbody blanket	D9090/90cm×90cm	Low speed	4.0	5.5	6.5
	Cardiac underbody blanket	D13090/130cm×90cm	Low speed	5.0	6.0	6.5

	Paediatric underbody blanket	D14090/140cm×90cm	High speed	4.0	5.5	6.0
	Pediatric full-underbody blanket blanket	D15080/150cm×80cm	High speed	4.0	5.0	6.0
	Paediatric spine underbody blanket	D16080/160cm×80cm	High speed	4.0	5.5	6.5
	Cath lab underbody blanket	D17090/170cm×90cm	High speed	5.0	6.0	6.5
	Adult spine underbody blanket	D18590/185cm×90cm	High speed	5.0	6.0	6.5
	Lithotomy underbody blanket	D19090/190cm×90cm	High speed	4.0	5.5	6.5
	Adult underbody blanket	D19580/195cm×80cm	High speed	4.0	5.0	6.0
	Adult half underbody blanket	D19590/195cm×90cm	High speed	5.0	6.0	6.5
	Full path underbody blanket	D20090/200cm×90cm	High speed	5.0	6.0	6.5
U	Chest and neck blanket	U5545/55cm×45cm	Low speed	3.0	4.5	4.5
	Larger chest and neck blanket	U6555/65cm×55cm	Low speed	3.0	4.5	4.5
	Belly blanket	U5540/55cm×40cm	Low speed	3.0	4.5	4.5
	Larger belly blanket	U8050/80cm×50cm	Low speed	3.0	4.5	4.5

	Leg blanket	U7540/75cm×40cm	Low speed	3.0	4.5	4.5
	Larger leg blanket	U10045/100cm×45cm	Medium speed	4.0	5.5	6.0

- Instructions for Use

1. Select the appropriate model and specification of the warming blanket based on the patient type and surgical requirements.The warming blanket comes in two types: cover blanket denoted by "U", placed over the patient, and mat blanket denoted by "D", positioned under the patient.
2. Open the packaging and take out the blanket.Spread the blanket flat according to the diagram on the label,ensuring it is flat without any wrinkles,and make sure the light-colored non-woven fabric faces the patient.During usage, ensure it comes in contact with the non-surgical area of the patient's body. For some models,it can be wrapped around the user as needed for clinical use to improve insulation. Pay attention not to compress the air duct when wrapping.
3. Insert the wind outlet of the device into the air inlet of the blanket, ensuring it is securely fixed. Use Velcro or straps to secure the connection of the air duct, preventing it from coming loose. Keep the air duct flat and straight, ideally positioning the wind outlet connection vertically with the inner end line of the blanket and placing it centrally and horizontally to enhance the warming effect.
4. Start the inflatable warming unit and preheat for 3-10 minutes to stabilize the temperature of the air outlet.
5. After preheating, cover the patient with the cover blanket or place the mat blanket under the patient. Secure the warming blanket to the operating table or bed edges using adhesive strips or non-woven fabric strips to prevent it from moving or slipping.
6. Straighten and flatten all the inflation channels of the warming blanket during use, allowing the non-woven fabric on the four sides to naturally hang down.
7. Adjust the output temperature and airflow of the inflatable warming unit as needed. The warm air delivered by the warming unit will heat the warming blanket.
8. Continuously monitor the patient's temperature for temperature regulation. Adjust as necessary if overheating or undercooling is observed.
9. After use, remove the warming blanket and dispose of it as medical waste.

- Important Notes, Warnings, and Instructions

1. Must be operated or used under the guidance of professional medical personnel.

2. The outermost welding line should be used as the outer boundary of the heating area of the warming blanket to distinguish between heated and non-heated areas.
3. To achieve better air warming effects, it is recommended to use the warming blanket of each model and specification according to the recommended wind speed level in the table.
4. Temperature deviations in areas other than the core area of the application site of warming blankets of each model and specification are not guaranteed.
5. When in use, securely connect the warming blanket to the device's duct, ensure the blanket is laid flat, do not reverse the blanket, with the light-colored breathable side facing the patient, switching sides may cause inability to warm up.
6. Do not use torn or damaged warming blankets, avoid sharp objects piercing them during use to prevent affecting their effectiveness.
7. Do not use blankets to transfer or move patients as it may result in the patient getting injured.
8. If the patient cannot undergo mechanical ventilation, do not cover the patient's head or airway with the warming blanket.
9. Do not place heavy or excessive objects above the blanket,including surgical drapes,pillows,or blankets; keep the air duct of the blanket clear to prevent airway blockage and affect warming effects.
10. The product is for single-use only; dispose of it as required by hospitals or environmental departments after use.

- Contraindications : None
- Manual Revision Date : May 31, 2024
- Production Date : Refer to the packaging seal
- Expiry Date : Store under specified conditions; shelf life of 3 years
- Storage Conditions : The packaged product should be stored in a clean environment with relative humidity not exceeding 80%, free from corrosive gases, cool, dry, well-ventilated
- Explanation of Tags


Do not reuse


Keep dry


Avoid sunlight

XII. Appendix B Electromagnetic Compatibility

NOTES:

1. The devices meet the electromagnetic compatibility requirements of YY 0505 and YY0834 standards.
2. Users should install and use them according to the electromagnetic compatibility information provided in the accompanying documents.
3. Portable and mobile RF communication devices may affect the warming devices. Avoid strong electromagnetic interference when using them, such as proximity to mobile phones, microwaves, etc.
4. For detailed guidelines and manufacturer's statements, refer to the appendix.

WARNING

1. The devices should not be placed near or stacked with other equipment. If it is necessary to be placed near or stacked, it should be observed and verified that it can operate normally in its configuration..
2. Class A equipment is intended to be used in industrial environments where there may be potential difficulties in ensuring electromagnetic compatibility in other environments due to conduction and radiation harassment by devices.
3. Except for the cables sold by the manufacturers of the devices as spare parts for internal components, the use of accessories and cables outside the specifications may cause an increase in emissions or a decrease in immunity of the devices

Sample Cable:

No	Name	Cable length (m)	Shield or not
1	Power cord	5	No
2	Air duct temperature probe wire	3	No

Appendix:

Guidance and manufacturer's statement — electromagnetic emission		
The devices are expected to be used in the following specified electromagnetic environments. The purchaser or user of the devices should ensure its use in such electromagnetic environments:		
Launch Test	**Compliance**	**Electromagnetic environments - Guidance**

RF emission GB 4824	Group 1	The devices use radio frequency energy only for their internal functionality. Therefore, their radio frequency emissions are very low, and the likelihood of causing interference to nearby electronic devices is minimal.
RF emission GB 4824	Category B	The device is suitable for use in all facilities of non-household and residential public low-voltage power supply grid not directly connected to the household.
Harmonic emission GB 17625.1	Category A	
Voltage fluctuation/flicker emission GB 17625.2	Compliance	

Guidance and manufacturer's statement — electromagnetic emission			
The devices are expected to be used in the following specified electromagnetic environments. The purchaser or user of the devices should ensure its use in such electromagnetic environments:			
Interference immunity test	**IEC 60601 test levels**	**Compliance levels**	**Electromagnetic environments - Guidance**
ESD (Electrostatic Discharge) GB/T 17626.2	±6kV Contact Discharge ±8kV Air Discharge	±6kV Contact Discharge ±8kV Air Discharge	The flooring should be made of wood, concrete, or ceramic tiles. If synthetic materials cover the floor, the relative humidity should be at least 30%.
Electric fast transient pulse group GB/T 17626.4	±2kV on power line ±1kV on input/output line	±2kV on power line	The mains power supply should have the quality typical for use in a commercial or hospital environment.
Surge GB/T 17626.5	±1kV Differential Mode Voltage ±2kV Common Mode Voltage	±1kV Differential Mode Voltage ±2kV Common Mode Voltage	The mains power supply should have the quality typical for use in commercial or hospital environments.
Power input line voltage temporary drop, brief interruption, and voltage fluctuation GB/T 17626.11	<5% UT, lasting 0.5 weeks 40% UT, lasting 5 weeks (60% temporary drop on UT) 70% UT, lasting 25 weeks (30% temporary	<5% UT, lasting 0.5 weeks 40% UT, lasting 5 weeks (60% drop on UT) 70% UT, lasting 25 weeks (30% drop on UT) <5% UT,	The power supply for the devices should have the quality typical for use in a commercial or hospital environment. If users of the devices need to operate continuously during a power outage period, it is

	drop on UT) <5% UT, lasting 5 s (>95% temporary drop on UT)	lasting 5 s (>95% drop on UT)	recommended that the devices be powered by uninterruptible power supply or batteries.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m, 50Hz	The power frequency magnetic field should have characteristics of power frequency magnetic field levels in typical locations of commercial or hospital environments.
Note: UT refers to the AC grid voltage before applying the test voltage			

Guidance and manufacturer's statement – electromagnetic emission			
The devices are expected to be used in the following specified electromagnetic environments. The purchaser or user of the devices should ensure its use in such electromagnetic environments:			
Interference immunity test	**IEC 60601 test levels**	**Compliance levels**	**Electromagnetic environments – Guidance**
RF conduct GB/T 17626.5	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication devices should not be used closer to any part of the devices than the recommended isolation distance, including cables. This distance should be calculated by a formula corresponding to the transmitter frequency. **Recommended isolation distance:d = 1.2 √P**
RF radiate GB/T 17626.3	10 V/m 80 MHz to 2.5 GHz	10 V/m	d = 0.35 √P for 80 MHz to 800 MHzd = 0.7 √P for 800 MHz to 2.5 GHzP is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W), and d is the recommended separation distance, in meters (m).The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field, and should be lower in level than compliance levels in each frequency range b.Interference may occur near equipment marked with the following symbols: 
Note 1: At the frequencies of 80 MHz and 800 MHz, use the formula for higher frequency bands.			

Note 2: These guidelines may not apply in all cases, as electromagnetic propagation is influenced by absorption and reflection from buildings, objects, and human bodies.
a. Fixed transmitting stations such as wireless (cellular/cordless) phones and ground mobile radio base stations, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts, and television broadcasts all cannot accurately predict their field strength theoretically. To evaluate the electromagnetic environment of fixed RF transmitters, an electromagnetic field survey should be considered. If the field strength measured at the location of devices exceeds the RF compliance levels for the applications mentioned above, observations of devices should be conducted to verify their proper operation. If abnormal performance is observed, corrective measures may be necessary, such as realigning or relocating devices. b. For the entire frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended isolation distance between portable and mobile RF communication equipment and devices

The device is expected to be used in an electromagnetic environment with controlled radiation RF interference.Based on the maximum output power of the communication equipment, purchasers or users of this device can prevent electromagnetic interference by following the recommended minimum distance between portable and mobile RF communication devices (transmitters) and devices.

The maximum rated output power of the transmitter./W	**The distance of isolation corresponding to different frequencies of the transmitter/m**		
	150kHz～80MHz $d=1.2\sqrt{P}$	**80MHz～800MHz** $d=0.35\sqrt{P}$	**800MHz～2.5GHz** $d=0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22

1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7

For the maximum rated output power of transmitters not listed in the above table, it is recommended to isolate the distance d in meters (m), which can be determined using the formula in the corresponding transmitter frequency column. Here, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W).

Note 1:At the frequencies of 80MHz and 800Mz, the formula for the higher frequency range is used.

Note 2:These guidelines may not be applicable to all situations where electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human bodies.

PATIENT WARMER SYSTEM

PWS-02

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